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| 10/506,543      | 10/13/2004  | Kjell Olmarker       | 003301-175          | 1315             |

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ALEXANDRIA, VA 22313-1404

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| EXAMINER |
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MONDESI, ROBERT B

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| ART UNIT | PAPER NUMBER |
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1652

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07/20/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

|                              |                        |  |                     |  |
|------------------------------|------------------------|--|---------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b> |  | <b>Applicant(s)</b> |  |
|                              | 10/506,543             |  | OLMARKER, KJELL     |  |
|                              | <b>Examiner</b>        |  | <b>Art Unit</b>     |  |
|                              | Robert B. Mondesi      |  | 1652                |  |

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 08 May 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 25-48 is/are pending in the application.
- 4a) Of the above claim(s) 25-45 and 47-48 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 46 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☒ Certified copies of the priority documents have been received in Application No. 1092919.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

This Office action is in response to the amendment filed May 8, 2007. **Claim 46** is under examination.

#### ***Restriction requirement***

This application contains **Claims 25-45 and 47-48** drawn to inventions nonelected with traverse in filed November 22, 2006. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

#### ***Withdrawal of Objections and Rejections***

The objections and rejections not explicitly restated below are withdrawn due to applicants' response in amendment filed May 8, 2007.

The objection to the specification for the improper use of Trademarks has been withdrawn in view of applicants' amendment to the specification in amendment filed May 8, 2007.

The objection to **claim 46** due to depending from a non-elected claim has been withdrawn in view of applicants' amendment to the claim in amendment filed May 8, 2007.

The rejection of **claim 46** under 35 U.S.C. 102(b) as being anticipated by Mita et al., US Patent No. 5,561,109 is withdrawn due to the applicants' amendment to the claim in amendment files May 8, 2007.

***Maintenance of rejections***

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

**Claim 46** remains rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

**Claim 46** remains rejected under 35 U.S.C. 102(e) as being anticipated by

Reuben et al. United States Patent Application Publication US 2002/0072596.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

**Claim 46** is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over **claims 1 and 23** of copending Application No. 10/092,919.

The above rejections were explained in the previous Office action.

### ***Response to applicants' arguments***

In regards to the rejection of **claim 46** under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, applicants assert that recites a specific biological activity, namely inhibition of a pro-inflammatory cytokine.

In addition, the specification provides peptides disclosed in WO 00/01730 as examples of peptides derived or derivable from lactoferrin (see page 10, lines 5-7). By this

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reference, the specification identifies a particular portion of the lactoferrin molecule characteristic of the claimed genus. Thus, a person of ordinary skill in the art can envision the detailed chemical structure of the encompassed genus of polypeptides.

Applicants' arguments have been considered but have not been found persuasive. Applicants may have amended the claim in order to include the limitation "inhibition of a pro-inflammatory cytokine"; however this is a functional characteristic that still fails to provide a nexus for the structure-function relationship of the genus of the lactoferrin derivatives. Applicants can certainly hope the lactoferrin derivatives will have an inhibitory characteristic with regards to pro-inflammatory cytokine but what is the structure of these lactoferrin derivatives. Applicants' reference of "essential subject matter" to a Foreign Patent Application is improper. Applicants cannot refer to compounds disclosed in WO 00/01730 as claimed subject matter.

The incorporation of **essential material** in the specification by reference to an unpublished U.S. application, **foreign application or patent**, or to a publication is improper. Applicant is required to amend the disclosure to include the material incorporated by reference, if the material is relied upon to overcome any objection, rejection, or other requirement imposed by the Office. The amendment must be accompanied by a statement executed by the applicant, or a practitioner representing the applicant, stating that the material being inserted is the material previously incorporated by reference and that the amendment contains no new matter. 37 CFR 1.57(f).

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In regards to the rejection of **claim 46** under 35 U.S.C. 102(e) as being anticipated by Reuben et al. United States Patent Application Publication US 2002/0072596 applicants assert that present claim 46 recites "peptides derived from lactoferrin." According to the present application as filed, "peptides derived from lactoferrin" are polypeptide fragments exemplified as those peptides disclosed in WO 00/01730, i.e. peptides derived from amino acid 12 to amino acid 40 of human lactoferrin.

Applicants' arguments have been considered but have not been found persuasive because Applicants' reference of "essential subject matter" to a Foreign Patent Application is improper. Applicants cannot refer to compounds disclosed in WO 00/01730 as claimed subject matter.

The incorporation of **essential material** in the specification by reference to an unpublished U.S. application, **foreign application or patent**, or to a publication is improper. Applicant is required to amend the disclosure to include the material incorporated by reference, if the material is relied upon to overcome any objection, rejection, or other requirement imposed by the Office. The amendment must be accompanied by a statement executed by the applicant, or a practitioner representing the applicant, stating that the material being inserted is the material previously incorporated by reference and that the amendment contains no new matter. 37 CFR 1.57(f).

In regards to the rejection of **claim 46** on the ground of non-statutory obviousness- type double patenting as allegedly being unpatentable over **claims 1 and**

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23 of copending application No. 10/092,919 applicants assert that Applicants will consider filing a Terminal Disclaimer, if appropriate, once allowable subject matter is determined.

***New Objection(s) and Rejection(s)***

***Specification***

The disclosure is objected to because of the following:

Applicants' have incorporated essential subject matter from the foreign application WO 00/01730.

The incorporation of essential material in the specification by reference to an unpublished U.S. application, foreign application or patent, or to a publication is improper. Applicant is required to amend the disclosure to include the material incorporated by reference, if the material is relied upon to overcome any objection, rejection, or other requirement imposed by the Office. The amendment must be accompanied by a statement executed by the applicant, or a practitioner representing the applicant, stating that the material being inserted is the material previously incorporated by reference and that the amendment contains no new matter. 37 CFR 1.57(f).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.



**Claim 46** is rejected under 35 U.S.C. 103(a) as being unpatentable over Mita et al. US Patent No. 5,561,109 in view of Rekdal et al., 1999.

Mita et al. teach a method of treating wounds, which includes the administering of lactoferrin (claim 1 of US. Patent No. 5,561,109).

Mita et al. do not teach the administering of lactoferrin derivatives.

Rekdal et al. teach lactoferrin derivatives and the enhanced antimicrobial activity of lactoferrin derivatives in comparison to lactoferrin (page 33, column 1, lines 1-14).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to create lactoferrin derivatives for the advantages of increasing lactoferrins' antimicrobial activity as taught by Mita et al. and Rekdal et al., see Rekdal et al. at page 33, column 1 lines 1-14.

### ***Conclusion***

No claims are allowed

Applicants' amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

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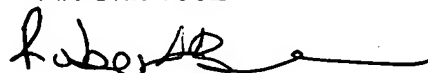
extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert B. Mondesi whose telephone number is 571-272-0956. The examiner can normally be reached on 9am-5pm, Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Robert B Mondesi  
Examiner  
Art Unit 1652

  
7-17-07